

- Engaging in a scheme to inflate its reported AWP for Zoladex® (*id.* ¶¶ 233, 236, 244), which included reporting “false,” “fraudulent” and “fictitious” AWP as part of an industry-wide “AWP Scheme” (*id.* ¶¶ 6, 8); knowing that those AWP were used as a reimbursement benchmark (*id.* ¶ 517(c));
- Marketing to providers the resulting spread or return on investment in connection with the so-called “AWP Scheme” (*id.* ¶¶ 239-40);
- Giving free samples to providers and, with respect to Zoladex®, “specifically told providers that they could and should bill for the free samples” (*id.* ¶ 242); and
- Providing rebates, chargebacks, hidden price discounts and/or other unlawful financial inducements “to further increase the provider’s spread and, therefore, their incentive to prescribe a particular . . . product” (*id.* ¶ 9).

According to the Attorney General, this conduct “constitutes deceptive acts or practices, fraud, false pretense, false promise, misrepresentation, concealment, suppression or omission of material fact in violation of A.R.S. § 44-1522(A)” (*id.* ¶ 517), which purportedly caused Arizona residents (Medicare Part B beneficiaries, MediGap payors, and non-Medicare private payors (*id.* ¶¶ 21 & 1 n.1) to suffer losses in connection with AWP-based payments for Zoladex®. The State seeks damages, civil penalties, declaratory and injunctive relief, restitution and disgorgement of profits (*id.* ¶¶ 1, 18-21).

There are no allegations in the First Amended Complaint that explain why the State of Arizona failed to assert these Zoladex® claims against AstraZeneca on behalf of Arizona individuals and entities until 2005. Indeed, as this Court has observed, by at least 2001, “there was a perfect storm of information that reflected the size of the spreads [between acquisition costs and AWP], largely because of the compelling information collected by the HHS Office of Inspector General (“OIG”).” *In re: Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007). Indeed, in December 2001, a class action lawsuit was filed in the District of Massachusetts on behalf of payors nationwide (including Arizona payors). (*Citizens for Consumer Justice* Complaint (“2001 Compl.”) (filed Dec. 19, 2001) [Docket Entry No. 1].) This

2001 complaint, which named AstraZeneca among the defendants, was premised on the very same allegations that now appear in Arizona's complaint filed four years later, namely that AstraZeneca, in connection with Zoladex® (2001 Compl. ¶ 25):

- Engaged in a “scheme” (*id.* ¶¶ 97, 103) of “artificially” and “fraudulently” inflating AWP for Covered Drugs above the “actual[]” average wholesale price by reporting inflated AWP’s (*id.* ¶¶ 70-72); knowing that AWP’s were used as reimbursement benchmarks by the Medicare Program (*id.* ¶ 97);
- Marketed to providers the resulting profit margins to be earned by prescribing the drugs (*id.* ¶¶ 95, 99);
- Gave free samples to providers and “encouraged providers to bill for so-called ‘free’ samples” (*id.* ¶¶ 95, 99); and
- Provided rebates, volume discounts, off-invoice pricing and/or other unlawful financial inducements “to increase the net profits for the prescribing doctor” and to induce them to prescribe the drug” (*id.* ¶¶ 99, 102).

Moreover, less than two years later, in July 2003, the Arizona Attorney General signed a Settlement Agreement and Release with AstraZeneca relating to Zoladex®, which was executed on September 4, 2003 (“2003 Settlement,” attached as Exhibit A to the Declaration of Katherine B. Schmeckpeper in Support of Defendants AstraZeneca Pharmaceuticals LP and Zeneca Inc.’s Motion to Dismiss the Plaintiff State of Arizona’s First Amended Complaint). The 2003 Settlement with Arizona,³ resolving Medicaid-related claims concerning Zoladex® explicitly identifies the State’s concerns regarding AstraZeneca’s purported misconduct “from January 1991 through the present, involving the marketing, sale and pricing of Zoladex for treatment of prostate cancer.”⁴ (2003 Settlement *passim*). In particular, the State asserted the same

³ AstraZeneca entered into similar agreements with the federal government and numerous other states.

⁴ In ruling on AstraZeneca’s motion to dismiss, the Court may properly consider the 2003 Settlement. *See Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33-34 (2001), *aff’d*, 311 F.3d 450 (1st Cir. 2002). Further, the Court may take judicial notice of the 2003 Settlement Agreement and properly consider it in connection with AstraZeneca’s motion. *See LoCicero v. Leslie*, 948 F. Supp. 10, 12 (D. Mass. 1996).

allegations in the 2003 Settlement that were asserted in the 2001 complaint and that it now asserts in the First Amended Complaint, namely that AstraZeneca:

- Engaged in a “scheme” (*id.* pmbl. ¶ F(iv)) of inflating AWP knowing that it was used by Medicaid and others for drug reimbursement (*id.* pmbl. ¶ F(iii));
- Marketed to providers the “spread” between the AWP and the discounted price, as profit or “return to practice” to be earned by prescribing the drugs (*id.* pmbl. ¶ F(iii));
- Gave free samples to certain physicians “knowing and expecting” those providers to bill for those free samples (*id.* pmbl. ¶ F(i)); and
- Provided deep discounts and/or other unlawful remuneration “to induce orders to purchase the drug Zoladex” (*id.* pmbl. ¶ F(iii)).⁵

In sum, the allegations that form the basis of the State’s Zoladex® claims against AstraZeneca were well known from at least 2001.

ARGUMENT

I. Zoladex® Claims Are Barred by the Statute of Limitations

All Zoladex® claims against AstraZeneca should be barred by the one-year statute of limitations that applies to claims brought under the Arizona Consumer Fraud Act. Under Arizona law, claims brought pursuant to the Consumer Fraud Act, A.R.S. § 44-1521, *et seq.*, are subject to the one-year statute of limitations prescribed by section 12-541(5) of the Arizona Revised Statutes. *See* A.R.S. § 12-541(5) (“There shall be commenced and prosecuted within one year after the cause of action accrues, and not afterward, the following actions: . . . (5) Upon a liability created by statute, other than a penalty or forfeiture.”); *Teran v. Citicorp Person-*

⁵ Additionally, despite allegations in the First Amended Complaint that AstraZeneca gave “hidden price discounts” on Zoladex®, in 2003, AstraZeneca began reporting to Arizona the Average Sale Price (“ASP”) for Zoladex® and certain other specified drugs, a calculation which includes all “volume discounts; prompt pay discounts; cash discounts; chargebacks; short-dated product discounts; free goods; rebates [footnote omitted]; and all other price concessions” offered on the sale of Zoladex®. *See* 2003 Settlement ¶ 18; *see also* CIA § III.D.2.b. This agreement has been posted by the U.S. Department of Health and Human Services, and is publicly available on its website. *See* <http://oig.hhs.gov/fraud/cia/agreements/AstraZeneca06042003.PDF>.

to-Person Fin. Cent., 706 P.2d 382 (Ariz. App. 1985); *Alaface v. Nat'l Inv. Co.*, 892 P.2d 1375 (Ariz. App. 1994); *Acuna v. Fireside Thrift Co.*, No. 05-3876, 2006 WL 1312528 (D. Ariz. May 11, 2006); *Murray v. W. Am. Mort. Co.*, 604 P.2d 651 (Ariz. App. 1979).

As a general matter, the statute of limitations does not run against the State under Arizona law. See A.R.S. § 12-510; see also *Tucson Unified Sch. Dist. v. Owens-Corning Fiberglass Corp.*, 174 Ariz. 336 (Ariz. 1993). However, an exception should be applied here where the State is asserting a claim that “belongs only to . . . some small and distinct section of the public,” *Trimble v. Am. Sav. Life Ins. Co.*, 733 P.2d 1131 (Ariz. App. 1986); see also *Diamond Benefits Life Ins. Co. v. Resolute Holdings*, 907 P.2d 63 (Ariz. 1995); *Warfield v. Gardner*, 346 F. Supp. 2d. 1033, 1047 (D. Ariz. 2004).

This is not a case where the Attorney General is pursuing claims on behalf of the public interest or public welfare. Rather, this is a case where the AG is effectively pursuing duplicative claims of a narrow group—Arizona individuals and entities that paid for Zoladex® on the basis of AWP—who have already sued AstraZeneca on their own behalf. Under these circumstances, the State should be held to the same statute of limitations as the private individuals and entities on whose “behalf” the State is purportedly bringing these claims. Because the State inexplicably delayed filing the Complaint until December 2005, despite widespread knowledge of the alleged conduct by 2001 (if not earlier), all Zoladex® claims should be barred by the statute of limitations.

II. Zoladex® Claims from 2001 Forward Should Be Dismissed

Alternatively, Zoladex® claims from 2001 forward should be dismissed under *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955 (2007) for failure to allege “a plausible entitlement to relief.” *Id.* at 1967, cited in *In re Citigroup, Inc.*, 535 F.3d 45, 52 (1st Cir. 2008). The State claims that AstraZeneca’s conduct with respect to Zoladex® was deceptive and otherwise violated section 44-1522(A). (Compl. ¶ 517; *see also id.* ¶¶ 233-44 (detailing Zoladex® allegations).) However, from at least 2001 forward, this claim is implausible, and hence legally insufficient, as it is flatly contradicted by the wealth of information available to the State concerning the acquisition price of Zoladex® and the “spread” between acquisition cost and AWP.

As this Court has already held, in 2001, there was a “perfect storm” of information concerning the “spreads” between AWP and transaction prices. *In re: Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 41 (D. Mass. 2007). Indeed, as described above, in 2001, a class action complaint was filed against AstraZeneca on behalf of Arizona individuals and payors for the very same Zoladex®-related conduct that the State now asserts in its complaint. (2001 Compl. ¶¶ 71-72, 95, 97, 99, 102, 103). Moreover, in 2003, the State of Arizona *itself* settled claims for Zoladex®, alleging that AstraZeneca had engaged in the very same conduct. (2003 Settlement pmbl. ¶¶ F (i), (iii)-(iv).) Given this knowledge, the State cannot plausibly claim that from 2001 forward, AstraZeneca “acted, used, or employed” any deception, deceptive act or practice in connection with the sale of Zoladex®. Accordingly, the State’s claims relating to Zoladex® from 2001 forward should be dismissed.

CONCLUSION

For the reasons set forth in Defendants’ Memorandum of Law, the entire Complaint should be dismissed as to AstraZeneca. If the Complaint is not dismissed in its entirety as to all

defendants pursuant to the points raised in Defendants' Memorandum of Law, for the reasons set forth above, AstraZeneca respectfully requests that the Court dismiss Zoladex® claims brought by the State of Arizona.

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered on September 19, 2008 to counsel for plaintiffs and to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, via LexisNexis File & Serve.

By: /s/ Katherine B. Schmeckpeper
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